NIH Policy on the Use of a Single Institutional Review Board (sIRB) for Multi-Site Research

Frequently Asked Questions

What types of studies are expected to use a single IRB (sIRB) under the new NIH Policy?

The sIRB policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards. Under the policy, "multi-site" is defined as two or more sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy. The policy recognizes that it may not always be possible to use an sIRB, and it provides for exceptions.

Are there any exceptions to the sIRB policy?

Exceptions to the sIRB policy will be made when review by the proposed sIRB would be prohibited by federal, tribal, or state laws, regulations or policies. Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a compelling justification for the exception. NIH will determine whether to grant an exception following an assessment of the need.

Why is NIH promoting the use of a sIRB for multi-site research studies?

The use of a single IRB of record for multi-site studies will help streamline the IRB review process and remove redundant hurdles to the initiation of such studies. The policy will allow research to proceed as effectively and expeditiously as possible. Eliminating duplicative IRB review is expected to reduce unnecessary administrative burdens and systemic inefficiencies while maintaining appropriate human subject protections. The shift in IRB workload away from redundant reviews is also expected to allow IRBs to concentrate more time and attention on the review of single site protocols, thereby enhancing research oversight.

Who is responsible for selecting the sIRB and when must this be done?

In the application/proposal for research funding, the applicant/offeror is expected to submit a plan describing the use of an sIRB that would be selected to serve as the IRB of record for all study sites. Where possible, the plan would include the registration number issued to the IRB by the HHS Office for Human Research Protections. For delayed-onset research, where the IRB cannot be identified, applications/proposals should include a statement that awardees will follow the sIRB policy and communicate plans to use a registered IRB of record to the funding NIH Institute/Center prior to initiating a multi-site protocol.

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What will happen if the applicant is not able to identify the sIRB, for example, because the sites are in disagreement about the selection?

If the sIRB cannot be identified prior to award, terms and conditions restricting human subjects research will be placed on the award. If sites are unable to agree on the sIRB, the IC funding the research will assist in resolving the matter. The sIRB will need to be identified before the release of funds under the award.

How will the sIRB policy be enforced?

Compliance with the sIRB policy will be a term and condition of award. Failure to comply with the terms and conditions of an award may result in enforcement actions, including termination of funding.

What is the role of the human subjects protections programs at a site that is part of a multi-site trial but not the site of the sIRB?

Except for the IRB review described in HHS regulations (45 CFR 46) human subjects protections programs at participating sites will be responsible for meeting all of their current responsibilities. Participating sites are also responsible for meeting other regulatory obligations, such as obtaining informed consent, overseeing the implementation of the approved protocol, and reporting unanticipated problems and study progress to the sIRB. Participating sites must communicate relevant information necessary for the sIRB to consider local context issues and state/local regulatory requirements during its deliberations.

Where can I find more information on the sIRB policy?

More information about the sIRB policy may be found on the OSP Website. NIH will continue to provide additional resources and guidance to this page prior to the implementation date.

Additionally, questions about the sIRB policy may be sent to SingleIRBPolicy@mail.nih.gov

When does the sIRB policy take effect?

The sIRB policy applies to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after May 25, 2017, all contract solicitation issued on or after May 25, 2017, and all NIH Intramural studies submitted for initial IRB review after May 25, 2017.

What is the difference between a central IRB and a sIRB?

Both are designed to help streamline IRB review, and the terms are sometimes used interchangeably. However, the term central IRB is generally used to refer to an IRB that reviews many different research protocols. Central IRBs are also sometimes referred to as independent IRBs. As used in the policy, the term single IRB refers to the IRB (which may be a central IRB or an institution-based IRB) that is selected to serve as the one IRB of record for the review of one protocol that will be carried out at many sites.